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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/055,686 01/18/2002 Lee Duen 01-1737 8760 7590 12/10/2004 EXAMINER Paul S. Tully PADMANABHAN, KARTIC McDonnell Boehnen Hulbert & Berghoff 32nd Floor ART UNIT PAPER NUMBER 300 S. Wacker Drive 1641 Chicago, IL 60606 DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/055,686	DUEN ET AL.
	Examiner	Art Unit
	Kartic Padmanabhan	1641
The MAILING DATE of this communication		th the correspondence address
renou for Reply		
A SHORTENED STATUTORY PERIOD FOR RETHE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFI after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, and all INO period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by standard part of the maximum after the maximum days after	N. R 1.136(a). In no event, however, may a re reply within the statutory minimum of thirty riod will apply and will expire SIX (6) MONT	(30) days will be considered timely.  HS from the mailing date of this communication.
Status		
1) Responsive to communication(s) filed on 15	5 November 2004	
	his action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) <u>1-53</u> is/are pending in the applicati	on.	
4a) Of the above claim(s) <u>6-8 and 10-53</u> is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-5 and 9</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) <u>1-53</u> are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Exami	ner.	
10)⊠ The drawing(s) filed on <u>18 January 2002</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)□ All b)□ Some * c)⊠ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
	or the defined copies not let	cerveu.
Attachment(s)		
Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/M	mary (PTO-413) lail Date
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date	3) 5) Notice of Inform	mal Patent Application (PTO-152)
Patent and Trademark Office	6)	

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### **DETAILED ACTION**

### Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 11/15/04 is acknowledged. The traversal is on the ground(s) that Groups I and II are not directed towards different invention. This is not found persuasive for reasons of record set forth in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

#### **Priority**

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Taiwan on 7/7/01. It is noted, however, that applicant has not filed a certified copy of the Taiwanese application as required by 35 U.S.C. 119(b).

#### Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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#### Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5. Claims 1-5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 6. Claim 1 is rejected as vague and indefinite for the recitation of an allergen fastened to the solid substrate because it is unclear to which layer of the substrate the allergen is fastened.

## Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 4-5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkh et al. (US Pat. 5,281,540) in view of Chen (WO 93/11437).

Merkh et al. teach a test array for performing assays, comprising a test card assembly. Test array 82 is preferably a laminate structure comprising a binding layer 83 adhered to a non-adsorbent substrate 85 which comprises a plastic film with an adhesive layer 87, for binding layer 83. Nitrocellulose is preferably the material of the binding layer. The non-adsorbent substrate is suitably a polyester film such as MYLAR plastic. The binding layer is preferably bound to the substrate by an adhesive layer, such as acrylic (Col. 13, line 39-Col. 14, line 1; Figure 8). However, the reference does not teach allergens on the substrate.

Chen teaches an allergen specific test for diagnosing allergies, wherein a solid carrier made of nitrocellulose or polystyrene may be used. Allergens may be fixed to these carriers in a density of 1-100 ug of allergen per square centimeter. Any type of allergen can be used on the carrier, such as microbial, flora, fauna, and chemical allergens (page 8). One example of an allergen for use with the invention is ovalbumin, a food allergen in egg (page 26).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to attach the allergens of Chen to the test substrate of Merkh et al. because Merkh at al. is generic with respect to the analyte specific receptors that can be attached to the

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nitrocellulose layer, and Chen attach allergens to nitrocellulose, thereby providing one with a reasonable expectation of success in using allergens with the substrate of Merkh et al.

11. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merkh et al. (US Pat. 5,281,540) in view of Chen (WO 93/11437) as applied to claims 1, 4-5, and 9 above, and further in view of Ness et al. (US Pat. 6,150,103).

Merkh et al. and Chen teach a modified substrate, as previously discussed. However, the references do not teach glass or silicon as the substrate.

Ness et al. teach biomolecule arrays, wherein the substrate may be glass, silicon, or synthetic organic polymers such as Mylar. (Col. 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use glass or silicon as the substrate as taught by Ness et al. with the modified device of Merkh et al. and Chen because Ness et al. teach that glass or silicon may be used just as well as Mylar for creating bimolecular arrays. Therefore, one would have had a reasonable expectation of success in using glass or silicon as the substrate with the modified device of Merkh et al. and Chen.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merkh et al. (US Pat. 5,281,540) in view of Chen (WO 93/11437) as applied to claims 1, 4-5, and 9 above, and further in view of Kita et al. (US Pat. 5,798,161).

Merkh et al. and Chen teach a modified substrate, as previously discussed. However, the references do not teach epoxy resin as the adhesive.

Kita et al. teach a device, wherein the adhesive layer of the reference may be acrylic or epoxy resins (Col. 12).

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It would have been prima facie obvious to one of ordinary skill in the art at the time of

the invention to use epoxy resin instead of acrylic as taught by Kita et al. with the modified

device of Merkh et al. and Chen because Kita et al. teach that epoxy and acrylic are both suitable

as adhesives, thereby providing a reasonable expectation of success in substituting one for the

other.

Conclusion

Claims 1-5 and 9 are rejected.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825.

The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan

Patent Examiner

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CHRISTOPHER L. CHIN PRIMARY EXAMINER

GROUP 1888/64/

Christian L. Chin

12/8/04